

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported) **March 1, 2010**

---

**VIVUS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation)

**001-33389**  
(Commission File Number)

**94-3136179**  
(IRS Employer  
Identification No.)

**1172 CASTRO STREET  
MOUNTAIN VIEW, CA 94040**  
(Address of principal executive offices, including zip code)

**(650) 934-5200**  
(Registrant's telephone number, including area code)

**N/A**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
- 
- 
- 

**Item 8.01. Other Events**

On March 1, 2010, VIVUS, Inc. issued a press release titled "VIVUS Announces FDA Acceptance of Qnexa® New Drug Application for Treatment of Obesity." A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Form 8-K and the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference into any of the Registrant's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

**Item 9.01. Financial Statements and Exhibits**

**(d) Exhibits.**

Exhibit No.	Description
99.1	Press Release dated March 1, 2010

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**VIVUS, INC.**

By: /s/ Lee B. Perry

**Lee B. Perry**

**Vice President and Chief Accounting Officer**

Date: March 1, 2010

3

---

**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 1, 2010

4

---



## **CONTACT:**

### **VIVUS, Inc.**

Timothy E. Morris  
Chief Financial Officer  
650-934-5200

### **Investor Relations:**

### **The Trout Group**

Brian Korb  
646-378-2923

### **Media Relations:**

### **Pure Communications, Inc.**

Dan Budwick  
973-271-6085

## **VIVUS ANNOUNCES FDA ACCEPTANCE OF QNEXA® NEW DRUG APPLICATION FOR TREATMENT OF OBESITY**

**MOUNTAIN VIEW, Calif., March 1, 2010** — VIVUS, Inc. (Nasdaq: VVUS) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the company's new drug application (NDA) for its investigational drug, Qnexa®, for the treatment of obesity. The target date for the FDA to complete its review of the Qnexa NDA is October 28, 2010. In previously announced pivotal phase 3 trials, patients treated with all three doses of Qnexa achieved significant weight loss compared to placebo, and significant dose-related improvements in a variety of secondary endpoints including reductions in cardiovascular, inflammatory and metabolic risk factors.

"The FDA's acceptance of the Qnexa NDA marks an important milestone in the development of Qnexa as a treatment for patients who are obese or overweight with co-morbidities," stated Leland F. Wilson, chief executive officer for VIVUS. "We believe that Qnexa, if approved, will play an important role in treating the millions of patients living with obesity and related diseases, and who are in need of safe and effective options."

### **About the Phase 3 Obesity Program**

The phase 3 clinical program, which evaluated Qnexa in more than 4,500 patients, was designed under a Special Protocol Assessment with the U.S. FDA and consisted of three trials: EQUATE (OB-301), EQUIP (OB-302) and CONQUER (OB-303). The EQUATE study was a 28-week randomized, double-blind, placebo-controlled, 7-arm, prospective trial with patients randomized to receive once-a-day treatment with mid- or full-dose Qnexa, the respective phentermine and topiramate constituents, or placebo. The average baseline BMI of the study population was 36.3 kg/ m<sup>2</sup> with an average baseline weight of 223 pounds. The EQUIP and CONQUER studies were 56-week, randomized, double-blind, placebo-controlled, 3-arm, prospective trials with patients randomized to receive once-a-day treatment with low-, mid-, or full-dose Qnexa, or placebo. In EQUIP, the average baseline BMI of the study population was 42.1 kg/m<sup>2</sup> with an average baseline weight of 256 pounds; in CONQUER, the average baseline BMI of the study population

VIVUS, Inc. 1172 Castro Street, Mountain View, CA 94040 Tel 650-934-5200 Fax 650-934-5389 [www.vivus.com](http://www.vivus.com)

was 36.6 kg/ m<sup>2</sup> with an average baseline weight of 227 pounds. All patients were asked to follow a hypocaloric diet representing a 500-calorie/day deficit and advised to implement a simple lifestyle modification program.

### **About Qnexa**

Qnexa (Q-NEX-uh) is an investigational drug being developed to address weight loss. Qnexa is a once-a-day, proprietary, oral, controlled-release formulation of low dose phentermine and topiramate, which is believed to address both appetite and satiety - the two main mechanisms that impact eating behavior - in one capsule. In phase 2 and 3 clinical data to date, Qnexa has demonstrated significant weight loss, glycemic control, reduction in sleep apnea events and improvement in cardiovascular risk factors.

### **About VIVUS**

VIVUS is a biopharmaceutical company developing innovative, next-generation therapies to address unmet needs in obesity, diabetes and sexual health. The company's lead product in clinical development, Qnexa®, has recently completed phase 3 clinical trials for the treatment of obesity. Qnexa is also in phase 2 clinical development for the treatment of type 2 diabetes and obstructive sleep apnea (OSA). In the area of sexual health, VIVUS is in phase 3 development with avanafil, a potentially best-in-class PDE5 inhibitor, and in phase 2 development of Luramist™ for the treatment of hypoactive sexual desire disorder (HSDD) in women. MUSE® (alprostadil), a first generation therapy for the treatment of ED, is already on the market and generating revenue for VIVUS. For more information about the company, please visit [www.vivus.com](http://www.vivus.com).

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimated" and "intend," among others. These forward-looking statements are based on VIVUS' current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, substantial competition; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; reliance on sole source suppliers; limited sales and marketing efforts and dependence upon third parties; risks related to the development of innovative products; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that future clinical studies discussed in this press release will be completed or successful or that any product will receive regulatory approval for any indication or prove to be commercially successful. VIVUS does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ended December 31, 2008 and periodic reports filed with the Securities and Exchange Commission.

